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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/823,181	03/30/2001	Jingyue Ju	0575/62948/JPW/ADM/BJA	9161

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EXAMINER

CHAKRABARTI, ARUN K

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 04/03/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/823,181	JU ET AL.
	Examiner	Art Unit
	Arun Chakrabarti	1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 26 February 2002.
- 2a) This action is FINAL.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1,4,5,11,12,14,15 and 59-73 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1,4,5,11,12,14,15 and 59-73 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
 If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a)  The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                           | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6 . | 6) <input checked="" type="checkbox"/> Other: <i>Detailed Action</i> .      |

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## **DETAILED ACTION**

### ***Election /Restriction***

1. Applicant's election with traverse of Group I in Paper No. 8 is acknowledged. The traversal is on the ground(s) that there is no burden in examining the claims of Groups II and III along with Group I. This is not found persuasive because as the restriction makes clear, additional search of Groups II and III would require review not only of the 1537 patents in class 536, subclass 22.1 for Group II, but also 165 patents for Group III, in class 266, subclass 168, as well as 8781 patents for Group I, class 435, subclass 6. Review of these additional searches is *prima facie* evidence of burden which is not rebutted.

The requirement is still deemed proper and is therefore made FINAL. The applicant has also added new claims 59-73 in Group I.

### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 4 and 73 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claim 4 is rejected over the use of improper Markush language. The phrase, "selected from the group consisting of" is suggested.

4. Claim 73 provides for the use of method of detecting DNA sequence for detection of SNPs and different diseases and/or purposes, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 73 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

#### ***Double Patenting***

5. Claims 1, 4, 5, 8, 14, 15, 59-62, and 65 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-22 of U.S. Patent No. 6,046,005. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1-22 of U.S. Patent No. 6,046,005 disclose basically and fundamentally the same method of instant claims 1, 4, 5, 8, 14, 15, 59-62, and 65, for sequencing DNA by detecting the identity of a dideoxynucleotide incorporated at the 3' end of a DNA

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sequencing fragment using mass spectrometry. The basic steps of detection of DNA of instant claims are same as claims 1-22 of U.S. Patent No. 6,046,005, which comprises a) attaching a chemical moiety via a linker to a dideoxynucleotide, b) terminating a DNA sequencing reaction with the labeled dideoxynucleotide, c) capturing the labeled DNA sequencing fragment on a solid surface, d) washing the surface, e) freeing the DNA sequencing fragment from the surface, and f) analyzing the fragment using mass spectrometry so as to sequence the DNA.

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CAR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CAR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CAR 3.73(b).

#### ***Claim Rejections - 35 USC § 102***

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

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8. Claims 1, 4-5, 7-8, 14-15, and 59-63, and 65-72 are rejected under 35 U.S.C. 102 (e) as being anticipated by Ju et al. (U.S. Patent 6,046,005) (April 4, 2000).

Ju et al teach a method for sequencing DNA by detecting the identity of a single or plurality of dideoxynucleotide incorporated to the 3' end of a DNA sequencing fragment using mass spectrometry (Abstract and Claims 1, 14, and 15, Figure 1 and Experimental Section), which comprises:

- a) attaching a chemical moiety via a linker to a dideoxynucleotide to produce a labeled dideoxynucleotide (Claims 1 and 15);
- b) terminating a DNA sequencing reaction with the labeled dideoxynucleotide to generate a labeled DNA sequencing fragment having a 3' end and the chemical moiety is attached via the linker to the 3' end of the DNA sequencing fragment (Claims 1 and 15 and Figure 1);
- c) capturing the labeled DNA sequencing fragment on a surface coated with a compound that specifically interacts with the chemical moiety attached via the linker to the DNA sequencing fragment, thereby capturing the DNA sequencing fragment (Claims 1 and 15);
- d) washing the surface to remove any non-bound component (Claims 1 and 15 and Experimental Section);
- e) freeing the DNA sequencing fragment from the surface by disrupting and cleaving the interaction between the chemical moiety attached via the linker to the DNA sequencing fragment

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and the compound on the surface (Claims 1 and 15 and Experimental Section and Figures 9-10);  
and

f) analyzing the DNA sequencing fragment using mass spectrometry so as to sequence  
the DNA (Claim 14).

Ju et al teach a method, wherein the interaction between the chemical moiety attached via  
the linker to the DNA sequencing fragment and the compound on the surface comprises a biotin-  
streptavidin interaction (Claims 19-20 and Experimental Section).

Ju et al teach a method, wherein the dideoxynucleotide comprises a cytosine or thymine  
with a 5-position and the linker is attached to the 5-position of cytosine or thymine (Figure 8 and  
Experimental Section).

Ju et al teach a method, wherein a plurality of different linkers is used to increase mass  
separation between different labeled DNA sequencing fragments and thereby increase mass  
spectrometry resolution (Column 7, lines 1-9 and column 9, lines 15-32).

Ju et al teach a method, wherein the interaction of the linker is cleaved by ultraviolet light  
(Figures 9-10).

Ju et al teach a method, wherein the chemical moiety comprises biotin, the labeled  
dideoxynucleotide is a biotinylated dideoxynucleotide, and the surface is a streptavidin-coated  
magnetic bead solid surface (Figure 1 and Experimental Section and Claim 20).

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Ju et al teach a method, wherein the biotinylated dideoxynucleotide is selected from ddATP-11-biotin, ddCTP-11-biotin, ddGTP-11-biotin, ddTTP-11-biotin and the compounds of claims 67-70 (Column 6, lines 35-64 and Figures 8-10).

Ju et al teach a method, wherein the steps (b) to (e) are performed in a plurality of connected containers (Experimental Section).

***Claim Rejections - 35 USC § 103***

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CAR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

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10. Claims 1, 4-5, 7-8, 11-12, 14-15, and 59-72 are rejected under 35 U.S.C. 103 (a) over Ju et al. (U.S. Patent 6,046,005) (April 4, 2000) in view of Arbo et al. (International Journal of Peptide and Protein Research, (1993), Vol. 42, pages 138-154).

Ju et al teach method claims of 1, 4-5, 7-8, 14-15, and 59-63, and 65-72 as described above including any linkers comprising a photo or chemically cleavable moiety.

Ju et al do not teach method, wherein the cleavable linkers are a derivative of 4-aminomethyl benzoic acid containing fluorine.

Arbo et al teach method, wherein the cleavable linkers are a derivative of 4-aminomethyl benzoic acid containing fluorine (Abstract and page 149, Column 2 to page 151, Column 1).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to combine and substitute the chemically equivalent cleavable linkers, which are a derivative of 4-aminomethyl benzoic acid containing fluorine of Arbo et al in the method of Ju et al., since Ju et al state, "In such linkers, the linker will comprise a cleavable moiety that is either photo or chemically cleavable (Column 7, lines 1-3)." By employing scientific reasoning, an ordinary practitioner would have been motivated to combine and substitute the chemically equivalent cleavable linkers, which are a derivative of 4-aminomethyl benzoic acid containing fluorine of Arbo et al in the method of Ju et al., in order to achieve the express advantages, as noted by Ju et al., of linkers which will comprise a cleavable moiety that is either photo or chemically cleavable.

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***Conclusion***

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Arun Chakrabarti, Ph.D., whose telephone number is (703) 306-5818. The examiner can normally be reached on 7:00 AM-4:30 PM from Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax phone number for this Group is (703) 305-7401.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group analyst Chantae Dessau whose telephone number is (703) 605-1237.

*Arun K. Chakrabarti*  
**ARUN K. CHAKRABARTI**  
**PATENT EXAMINER**

Arun Chakrabarti,

Patent Examiner,

March 19, 2002